Custom Services International
INCORPORATED

October 25, 1999

Dockets Management Branch
Division of Management Systems and Policy
Office of Human Resources and Management Services
Food and Drug Administration
5630 Fishers Lane, Room 1061, (HFA-305)
Rockville, MD 20852.

Gentlemen:

Reference : 99D-2335

This letter is being written to contain some of the comments we have developed regarding the above referenced guidance document. We have, under a separate cover, requested an extension to provide more complete comments, however, these have been prepared and submitted prior to October 28, 1999 to meet the current deadline. For ease of organization, we will submit comments to the document from the front to the back using the page numbers of the "pdf" document provided.

Comment #1: Premise of the Guidance Document: The document states that it contains "guidance on the basic regulatory requirements set forth in FDA's regulations that all manufacturers and importers must consider when they plan to market medical gloves." This statement is based on the premise that Docket 98N-0313 will be enacted. As such, it can only be future guidance and not the guidance which would apply to existing 510(k) releases or potential releases filed prior to finalization of rule changes proposed by Docket 98N-0313. This guidance should only be effective after the Rule change is effective. As a small minority business, we are concerned that this guidance be applied uniformly to all manufacturers. In our experience, the regulations have not been applied evenly to both domestic manufacturers and importers. This unduly penalizes small business.

Comment #2: Page 14: The proposed guidance states: "Powdered gloves. ASTM, FDA and industry **are developing a standard** for measuring the donning powder on a powdered glove." (Emphasis added). This standard is being prepared by the Maximum Powder Task Group of ASTM. It has been balloted and negatives have been received. The precision of the method has also been questioned. As such, with no current method to test the quantity of powder on a powdered device, regulations concerning testing the amount of powder are premature.

Comment #3 Page 14: The proposed guidance states: "FDA is proposing in the noted regulation that all surgeon's gloves and patient examination gloves bear labeling that states the powder per glove and state the upper limit recommended by FDA which is proposed to be no more than 120

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mg per glove." While the desire to minimize powder is one that should be enacted, and there is clear indication in the medical literature that powder causes adverse effects on healthcare workers who inhale it as a nuisance dust at levels which are in excess of OSHA standards and offer an alternate route of exposure to known protein allergens and endotoxins which may be independently allergenic, as well as on patients who end up with glove powder contaminating wounds, the limitation chosen would have to be consistent with the manufacturer's ability to control the powder. The data presented at ASTM (6/28/99) indicates that 120 mg. per glove is not currently achievable by industry. For examination gloves while the average is 126.6 mg/glove, only 66.6% were less than 150 mg. For surgeon's gloves, only 50% were less than 120 mg., and the averages were substantially higher.

Comment #4 Pg 34: The guidance document states: "Gloving cream is classified under 21 CFR 878.4470 as a Class I device. Gloving cream was exempted from premarket notification requirements by a notice in the Federal Register, Vol. 59, page 63010, December 7, 1994. If the intended use of the cream is different from that described in 21 CFR 878.4470, i.e., "...lubricating the user's hand...," the cream is not exempt from the 510(k) requirements." Many creams and lubricants are now on the market that make claims about blocking latex proteins or that they are barriers to contact with latex. These have been marketed without any demonstration of compatibility or effectiveness. Additionally, as the regulations become more specific about proteins, because it is this that causes the allergic reactions, creams which have water bases that can leach proteins out may increase the allergy problem. It is essential that the agency review its position on glove creams and enforce 510(k) for those creams which are making claims other than ease of donning.

Comment #5 Pg. 36: The guidance document states: "Non-medical gloves, commonly known as utility, industrial, or general purpose gloves, are used for tasks that do not involve contact with patients or body fluids. Therefore, they are not regulated by the FDA." General purpose gloves are often used by housekeeping staffs to prevent contact with body fluids during cleaning. OSHA requirements are that protective devices are to be provided when there is the potential for contact with a bodily fluid. The gloves that are provided are often general purpose gloves. In this scenario, the gloves should be regulated as a medical device. To do otherwise leaves the potential that all gloves are made to a standard and it is the rejects that become general purpose. This exposes a significant portion of the work force who uses gloves in not medical situations to prevent exposure to an unacceptable level of risk.

Comment #6 Pg 38: The guidance document states: "....manufacturers should establish a specification for the amount of powder on a glove." To the extent that there is a regulation that indicates a level above which the glove should not exceed, then a specification would have to be established. However, as powdering of gloves is done is a slurry process, the amount deposited on any individual glove is subject to wide variation. Given current methodology, the only specification that could be established is the standard rule that glove powder is about 10% of the weight of the glove. With average glove weights around 2 grams, this would be about 200 mg. of powder. This is well in excess of the regulation of 120 mg. proposed by the FDA. We could see a requirement that manufacturers "establish a specification to limit the amount of powder on a glove" producing a manufacturer obligation to keep powder as low as the process allows, but any

other specification is outside the scope of current technology.

Comment #7 Pg. 38: The guidance document states: all new dusting powder for use with surgical gloves must be approved for marketing by the PMA process (21 CFR 814). The agency has released for distribution a patient examination glove which contains oat starch as the lubricant. This lubricant is a dusting powder and has not submitted to the 510(k) process, however it is lawfully sold. This would not be consistent with the guidance presented which is unchanged from currently enacted guidance documents.

Comment #8 Pg. 39: The guidance for the use of scientific literature should be referenced so that proper information is received by the agency and that guidance documents are consistent.

Comment #9 Pg. 52: The guidance should reference ASTM Standard D6355-98 which was designed to provide a proper protocol for the conducting of a Human Draize Test.

Comment #10 Pg 63: Statements of identity should include a requirement that natural rubber latex used in combination with any polymer should have to be labeled as containing NRL.

Comment #11: Pg. 64 The Guidance document contains language that the FDA is requiring for labeling. This language reads as follows: "Caution: This product contains natural rubber latex which may cause allergic reactions. FDA recommends that this product contain not more than 120 mg powder and 1200 µg ex-tractable protein per glove. This product contains no more than [insert level] mg powder and no more than [insert level] µg extractable protein." The public has been accustomed to see a warning that is reflected based in dm^2. Since this is the basis of the standard calculation accepted by the FDA, it is not appropriate to convert to another unit of measure as this could undo education which is already part of many manufacturer's literature and not consistent with the underlying standards. This commenter respectfully requests that the requirement be changed to be consistent with the standards.

Comment #12 Pg 64: The guidance document contains language that the FDA will require for synthetic gloves. This language reads: "Caution: Glove powder is associated with adverse reactions. FDA recommends that this product contain no more than 120 mg powder per glove. This product contains no more than [insert level] mg powder per glove." Glove powder is not associated with adverse reactions *per se*, but instead is a carrier for latex proteins which may cause reactions, or endotoxins which may cause allergic reactions independently. The better statement would be "Caution: Glove powder may cause allergic reactions. This product contains no more than [insert level] mg powder per glove."

Comment #13 Pg. 65: See the comment re the protein caution statement shown above (Comment # 11) as that comment is applicable here.

Comment #14 Pg 65: Under no circumstances should a latex glove be used on a latex allergic individual regardless of the protein level. It is counterproductive to the care of those with latex allergy to recommend use of a latex glove when latex precautions are indicated. This statement regarding the use of a latex product on a latex sensitive indivusla should be removed.

Comment #15 Pg 65-66: Shelf life labeling is required for other medical devices made of latex. However, a methodology for how shelf life is to be determined has not been specified. For new manufacturers which do not have real time data (many existing manufacturers would) a validated accelerated method is not available. Since to validate a method would take five years (an accelerated method against a real time method), a provisional protocol should be specified by the Agency that will be acceptable so manufacturers can use that method or validate a method against the recommendation. Since the method has been drafted but has not been made available at the time these comments were written, comments on how shelf studies and expiration dates cannot be reasonably made. This is a further justification for an extension in comment period so that all of the information can be made available.

Comment #16 Pg 66: Since the requirement is for USP absorbable dusting powder or one released by PMA, if a label declaration is required, then the product should be properly specified and the PMA referenced for OSHA requirements to be met. OSHA requires that a MSDS be obtainable for such an item. Without a clear specification, the user would be unable to determine the material.

Comment #17 Pg. 68: The guidance document states that 2 mg of residual powder should be on "powder free gloves. Many manufacturers already have releases which allow as much as 5 mg. The ASTM standard has a phased in reduction to 2 mg by 2002 which is consistent with the industry's ability to reduce residual powder. This method was adopted though the consensus method with FDA participation. FDA should abide by the standards process as required by law. This method provides free access to all manufacturers and allows large and small business to be treated equally.

Comment #18 Pg. 71: See Comment #9

Comment #19 Pg 82: Glove powder should meet the requirements of the U.S. Pharmacopeia or have an appropriate PMA release for use. This is the requirement of the regulation. See Comment #7. Failure to state that a PMA is required in this text misleads the user into thinking a substantial equivalence analysis is all that is necessary. This is contrary to other guidance in this manual.

Comment #20 Pg. 125: The Quality System Regulation. This chart is somewhat confusing as all of the feedback loops are not present. Additionally, a key person, from the design control perspective is left out. The customer. As consumer feedback is required and is an integral part of the design control regulation, which is now a foundation of the quality system, the paradigm should reflect their inclusion. See Attachment "A" to this comment letter.

Comment #21 Pg. 126: Quality System and QA audits. This chart also has feed back loops missing. See Comment #20 and Attachment "B" to this letter.

Comment #22 Pg 131: Design Control. This chart would not lead to compliance by manufacturers with the design control regulations, because the compliance points are not clear. Please see Attachment "C"

Comment #23 Pg 144-154: This section describes the necessity for compliance with various aspects of the QSR. It would make sense for the Agency to include the information organized as the new paradigm for inspection is; in management systems. This would provide a clear guidance for how the user of this compliance manual should structure their systems and assist small businesses in preparing for inspections and record maintenance and collection.

Comment #24 Pg 196: This section of the guidance discusses the importers obligation to hold material for testing. It is important that the importer have some information as to how long the process will take for proper inventory management and cash flow. As testing of imported products reverses the burden of proof (the burden is on the importer) to provide compliance it places the importer at a significant competitive disadvantage to the U.S. dipper where the burden is on the Agency to prove the product is adulterated. Traditionally, the time was 30 days. Now it is taking almost 60 days. It is important that decisions be made because storage and handling is a significant cost and interferes with the small business's ability to compete.

While the above list of comments is not exhaustive, it does provide both a basis for consideration and for the granting of an extension for comments.

Should you have any questions about these comments, or require further information, please contact the undersigned.

Sincerely,

CUSTOM SERVICES INTERNATIONAL INC.

Lillie C. Thomas, M.S.
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